

## **Laboratory Registration/Select Agent Transfer Program Application for Laboratory Registration**

### ***Information on Select Agents Containing Recombinant DNA***

Before beginning this section, refer back to the *Background Information/Certification and Signature* page of this application. Use the BMBL, the BMBL supplement page (Attachment) and/or the *NIH Guidelines for Research Involving Recombinant DNA* to determine the recommended BSL for the various types of work you will do with each of the select agents you listed.

Your responsible facility official will determine whether you should use the BMBL or the *NIH Guidelines* to determine BSL for recombinant DNA work at your institution. The decision as to which guideline to use is to be based on which document is used as a basis for your institution's policies and procedures for work with those select agents. Institutions using recombinant DNA for large animal studies or in large scale production must complete the applicable sections of the assessment instrument based on the *NIH Guidelines*, as there are no corresponding sections in the BMBL.

If you do the same type of work with several select agents at the same safety level, in one laboratory, under the supervision of one principal investigator, you may consider those select agents as one group and give us the required information for all of them on this form.

If your facility will do more than one type of work with recombinant DNA under this regulation, will work with agents having different BSL requirements, or will do the work in several laboratories, photocopy this form as many times as necessary, then complete a different form for each group of select agents, BSL requirement or laboratory.

#### **Section 1**

**What work with select agents involving recombinant DNA will you describe on this form ?**

List the Select Agent(s) here: \_\_\_\_\_

What laboratory will you use for work with these select agents (Building, Room Number)? \_\_\_\_\_

Will you be doing only Clinical/Diagnostic work with these select agents? ( ) Yes ( ) No

Is your laboratory a CLIA regulated laboratory for purposes of work with the select agent(s) listed?  
( ) Yes ( ) No.

If yes, what is the CLIA registration number for this laboratory (or for your facility, if the facility has a single number)? \_\_\_\_\_

(If the only work you do with this select agent or group of select agents is covered by CLIA, you may be exempt from the requirements of 42 CFR 72.6. Refer to the regulation (Attachment 1))

Will you be working with isolates/concentrates of these select agents? ☐ Yes ☐ No

If yes, what BSL does the BMBL (and supplement) or the *NIH Guidelines* recommend? BSL \_\_\_\_\_

Will you use laboratory animals (e.g., mice, guinea pigs) for any of your work with these select agents?  
☐ Yes ☐ No

If yes, what ABSL does the BMBL (and supplement) or the *NIH Guidelines* recommend? ABSL \_\_\_\_\_

Will you use large animals (e.g., sheep, cattle) for any of your work with these select agents? ☐ Yes  
☐ No

If yes, what BLN does the *NIH Guidelines* recommend? BLN \_\_\_\_\_

Will you be doing any large scale (LS) ("production level") work with any of these select agents?  
☐ Yes ☐ No

If yes, what BL-LS does the *NIH Guidelines* recommend? BL-LS \_\_\_\_\_

## Section 2

### **Descriptions of laboratories and procedures for work with select agent recombinant DNA at your institution:**

On a separate sheet:

State the name of the individual responsible for laboratory (e.g., principal investigator or laboratory supervisor).

Describe briefly (1-2 sentences) type of work being done with this select agent(s) listed above.

Describe briefly (1-2 sentences each): 1) how you control access to laboratory area where these select agents are used, 2) how you ensure adequate training and proficiency testing for personnel working with agent(s), 3) where you store the select agent(s) (e.g., location of refrigerator or freezer), 4) proposed method of storage or disposal of select agent when work is complete, and 5) method for managing a spill or accidental exposure to the select agent(s).

Attach a sketch/floor plan (not blueprints) for laboratory where work will be performed - show entry, location of BSC, incubators, freezers, autoclaves, and other equipment specified in the BMBL, *NIH Guidelines* or other reference document as recommended for work with an agent at that BSL. Mark location of air intake and exhaust vents.

Describe the air-handling system for the laboratory where the work will be performed (e.g., single pass or re-circulation, type of filters, method for handling safety cabinet exhaust)

## Section 3

### **Assessment of your laboratory based on recommendations of BMBL or *NIH***

**Guidelines:**

The appendix to this application package contains laboratory assessment instruments based on the BMBL and on the *NIH Guidelines*. The BMBL based assessment instruments are labeled "BSL2", "BSL3", "BSL4", "ABSL2", "ABSL3", "ABSL4". The NIH Guidelines based assessment instruments are labeled BL1 - BL4, BL2N - BL4N (for large animal work), and BL1 (large scale) - BL3 (large scale) (for large volume or production work).

Select the appropriate assessment instruments based on the work you will be doing with the select agent(s) listed above and your responses in section 1. (e.g., if you are working with an agent at BL3, and doing large animal studies with that agent at BL3N, complete the BL3 and BL3 N sections of the assessment instrument).

Use **either** the BMBL **or** the *NIH Guidelines* - based assessment instruments, depending on whether your institution uses the BMBL or the *NIH Guidelines* as the basis for its safety policies and procedures. If you are working with large animals studies or production quantities, complete those assessment instruments from the *NIH Guidelines*.

If yours is a DOD laboratory working under 32 CFR 626 and 627, you may substitute the relevant sections of that regulation. Attach a copy of the relevant section of the regulation, with a "Yes", "No" or "N.A." noted in the margin for each item, with the responsible facility official's initials on each page.

If your laboratory works with this select agent under other federal regulations or guidelines (e.g., FDA, EPA or USDA), that have different requirements than the BMBL or *NIH Guidelines*, please complete as much of the relevant BMBL or *NIH Guidelines* based assessment instrument as possible, and attach a copy of any other federal regulation or guideline, marked to show us where it differs from the BMBL or *NIH Guidelines*, and initialed by the responsible facility official.

Attach a copy of each completed **Laboratory Assessment Instrument** to this form.